FEB 0 7 2002

# 501(K) SUMMARY

K020107

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| Submitter: | Cynosure, Inc.<br>10 Elizabeth Drive<br>Chelmsford, MA 01824 |
| Contact: | George Cho<br>Senior Vice President of Medical Technology |
| Date Summary Prepared: | January 10, 2002 |
| Device Trade Name: | SMARTEPIL |
| Common Name: | Medical Laser System |
| Classification Name: | Instrument, surgical, powered, laser<br>79-GEX<br>21 CFR 878.48 |
| Equivalent Device: | Acclaim Laser |
| Device Description: | The SMARTEPIL Laser is a pulse Nd:YAG laser utilizing the Nd-YAG crystal as the lasing medium. It is a pulsed laser with a wavelength of 1064nm.<br><br>Laser activation is either by a finger switch or a footswitch. Overall weight of the laser is 200lbs, and the size is 92cm x 40cm x 80cm (H x W x D).<br><br>Electrical requirement is 220VAC, 13A, 50-60 Hz, single phase. |
| Intended Use: | The SMARTEPIL Laser is indicated for benign vascular lesions and hair removal. |
| Comparison: | The SMARTEPIL Laser is substantially equivalent to the Cynosure Acclaim Laser. They are both pulse Nd:YAG lasers for the identical indications for use. |
| Non-clinical Performance Data: | None |
| Clinical Performance Data: | None |
| Conclusion: | The SMARTEPIL Laser is another safe and effective device for dermatological vascular lesions and hair removal application. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2002

Mr. George Cho
Senior Vice President, Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K020107
Trade/Device Name: SMARTEPIL
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 10, 2002
Received: January 11, 2002

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020107

Device Name: SMARTEPIL

Indication for Use:

The SMARTEPIL Laser is indicated for benign vascular lesions and hair removal.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per21 CFR 801.109)

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative and Neurological Devices**

**510(k) Number** K020107